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10/599,722	09/19/2008	Patrick Lewis Blott	SMNPH.008APC	3283

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EXAMINER

SU, SUSAN SHAN

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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10/05/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/599,722	Applicant(s) BLOTT ET AL.	
	Examiner SUSAN SU	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/5/2007, 12/30/2008, 1/30/2009, and 10/19/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-8 & 11-24 are pending, of which claims 1-8 were amended on 26 August 2009 and Claims 11-24 were added on the same day. No new matter is found. All claims are examined on the merits.

Specification

1. The disclosure is objected to because of the following informalities: the disclosure is unclear due to the choice of words. In paragraphs [0035], [0057], [0068], [0093], [0099], [0108], [0118], [0125], and [0138] the term "single integer" is used in reference to a combination of two or more devices (e.g. first device and means for aspirate flow regulation and/or means for supply flow regulation) or two structures (e.g. a pipe and a tube). While the dictionary definition for "integer" is "a whole number," it is believed in this case the Applicant intends to mean that the combination of the devices and/or structural features would form a single integral unit.

Appropriate correction is required.

35 USC § 112, 6th Paragraph

2. With regard to Applicant's "means for providing simultaneous aspiration and irrigation," "means for flow regulation," means for aspirate flow regulation," "means for supply flow regulation" of claims 1, 2, 6, 7, 13, & 14, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

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- (A) the claim limitations must use the phrase "means for" or "step for;"
- (B) the "means for" or "step for" must be modified by functional language; and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

- (A) performs the function specified in the claim,
- (B) is not excluded by any explicit definition provided in the specification for an equivalent, and
- (C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation.

See MPEP 2183.

Regarding Claims 1-8 & 11-14, Applicant appears to not meet the requirements set forth in MPEP §2181, because the claim limitation “means for providing simultaneous aspiration and irrigation” is further modified by some structure, material, or acts recited in the claim.

Additionally regarding Claims 1, 2, & 4, the recitation “means for flow regulation,” “means for aspirate flow regulation” and “means for supply flow regulation” appear to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8, 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In Claims 1, 6, & 7, the claim limitation “means for providing simultaneous aspiration and irrigation” uses the phrase “means for” or “step for,” but it is modified by some structure, material, or acts recited in the claim. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph, because said claim limitation is modified by sufficient structure (e.g. “at least one device for moving fluid through the fluid flow path”).

Similarly for Claims 13 & 14, the claim limitation “means for flow regulation” is modified by the structure of “a flow regulator,” which precludes the application of 35 U.S.C. 112, sixth paragraph.

If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that the phrase “means for” or “step for” is clearly **not** modified by sufficient structure, material, or acts for performing the claimed function.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that it will clearly not be a means (or step) plus function limitation (e.g., deleting the phrase “means for” or “step for”).

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Claims 2-8 and 11-14 are also rejected for being dependent on Claim 1, which is indefinite for the reasons stated above.

6. Additionally, claim element “means for flow regulation” of Claim 1, “means for aspirate flow regulation” and “means for supply flow regulation” of Claims 2 & 4 are means (or step) plus function limitations that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. There lacks an explicit disclosure of what structure or material would constitute the means for performing said recited functions.

Applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

- (a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or
- (b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claims 2-8 and 11-14 are additionally rejected for being dependent on Claim 1, which is indefinite for the reasons stated above.

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7. Furthermore, Claims 2 & 6 recite "a second device for moving fluid *through the wound applied to irrigant in the fluid supply tube* upstream of and towards the wound dressing." The Examiner finds the recitation unclear. The Examiner makes her examination by interpreting said recitation to read "a second device for moving fluid through the wound, wherein the second device is configured to supply an irrigant toward the wound dressing through the fluid supply tube upstream of the wound dressing." Appropriate correction is requested.

8. The use of the term "relatively" in independent Claims 1, 15, and 20 render the claims indefinite. Claims 2-8, 11-14, 16-19, and 21-24 are dependent claims and therefore also rejected for being indefinite.

9. Claim 3 recites the limitation "*the* first device" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. It is believed that Claim 3 should be dependent on Claim 2.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

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Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-4, 6, 7, 11-16, 18, & 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Risk, Jr. et al. (US 6,824,533, "Risk").

With regard to Claim 1, Risk teaches an apparatus for aspirating, irrigating and/or cleansing wounds, the apparatus comprising:

- a fluid flow path comprising a conformable wound dressing (14), having a backing layer (602) which is capable of forming a fluid-tight seal or closure over a wound, the backing layer comprising a wound-facing face, a fluid supply tube (18), and a fluid offtake tube (20);
- a fluid reservoir (24) in communication with the fluid supply tube;
- means comprising at least one device (110 and/or 72) for moving fluid through the fluid flow path, the apparatus being configured such that fluid may be supplied to fill the flow path from the fluid reservoir via the fluid supply tube while fluid is aspirated through the fluid offtake tube; and
- means for flow regulation (50) in communication with either the fluid supply tube or the fluid offtake tube.

The language "for providing simultaneous aspiration and irrigation" is held to be intended use (since it fails the requirements for means-plus-function and does not invoke 35 U.S.C. 112, 6th paragraph). While features of an apparatus may be recited

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either structurally or functionally, claims directed to a device must be distinguished from the prior art in terms of structure rather than function, because device claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. The apparatus of Risk has separate irrigation and aspiration tubes and pumps, thus it is capable of allowing simultaneous aspiration and irrigation.

With regard to Claims 2 & 6, Risk also teaches that the at least one device for moving fluid through the fluid flow path is a first device (110) for moving fluid downstream of and away from the wound dressing, and the apparatus comprises at least one of:

- a second device (72) for moving fluid through the wound, wherein the second device is configured to supply an irrigant toward the wound dressing through a fluid supply tube upstream of the wound dressing;
- means for aspirate flow regulation (134), connected to a fluid offtake tube,
- and
- means for supply flow regulation, connected to a fluid supply tube.

With regard to Claim 3, Risk also teaches that the apparatus is configured to direct fluid in the fluid offtake tube downstream of the wound dressing to a collection vessel (26), and the first device is in communication with the collection vessel.

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With regard to Claim 4, Risk also teaches that the at least one device for moving fluid through the fluid flow path is a fixed throughput device (pump 110 is disclosed to operate at maximum vacuum and the amount of suction is varied by closing valve 130, see Col. 6 line 57 to Col. 7 line 29), and the means for flow regulation also comprises at least one of:

means for supply flow regulation, connected to the fluid supply tube, and
means for aspirate flow regulation (valve 130, controlled by controller 50),
connected to the fluid offtake tube.

With regard to Claim 6, Risk also teaches that the at least one device for moving fluid through the fluid flow path is a first device (110) for moving fluid downstream of and away from the wound dressing, and the means for providing simultaneous aspiration and irrigation of the wound further comprises at least one of a second device (72) for moving fluid through the wound, wherein the second device is configured to supply an irrigant toward the wound dressing through a fluid supply tube upstream of the wound dressing.

With regard to Claims 7 & 11, Risk also teaches that at least one of the first device and the second device is a fixed throughput device (pump 110 is set to operate at maximum suction, Col. 7 lines 27-29), and the means for providing simultaneous aspiration and irrigation of the wound also comprises at least one of means for supply flow regulation connected to the fluid supply tube and means for aspirate flow regulation connected to the fluid offtake tube.

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With regard to Claim 12, Risk also teaches that the at least one device for moving fluid through the fluid flow path comprises a device (110) in communication with the fluid offtake tube and configured to move fluid downstream of and away from the wound dressing.

With regard to Claims 13 & 14, Risk also teaches that the means for flow regulation is a flow regulator (50) in communication with the fluid supply tube and/or the fluid offtake tube.

With regard to Claim 15, Risk teaches a method of treating a wound to promote wound healing, the method comprising:

providing a fluid flow path, the fluid flow path comprising a conformable

wound dressing (14), having a backing layer (602) forming a fluid-tight

seal over a wound, the backing layer comprising a wound-facing face, a

fluid supply tube (18), and a fluid offtake tube (20);

moving fluid (Col. 8 lines 53-61) from a fluid reservoir through the fluid flow path;

regulating (Col. 5 lines 15-28) the amount of fluid that flows through the fluid supply tube; and

regulating (Col. 6 lines 57-67) the amount of fluid that flows through the fluid offtake tube;

wherein regulating the amount of fluid that flows through the fluid supply tube

is independent of (controller is fed by different sensors to determine if fluid

has been dispensed and how much suction should be applied, see Col. 5

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lines 35-42 and Col. 6 lines 50-56) regulating the amount of fluid that flows through the fluid offtake tube.

With regard to Claim 16, Risk also teaches that both regulating the amount of fluid that flows through the fluid supply tube and regulating the amount of fluid that flows through the fluid offtake tube comprise regulating the amount of fluid with a pump (110).

With regard to Claims 18 & 19, Risk also teaches that at least one of regulating the amount of fluid that flows through the fluid supply tube and regulating the amount of fluid that flows through the fluid offtake tube comprises regulating the amount of fluid with a regulator, wherein the regulator is a valve (130, which is controlled by controller 50).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 5, 8, & 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Risk in view of Lockwood et al. (US 6,752,794, "Lockwood").

With regard to Claims 5 & 8, Risk does not explicitly teach that the at least one device for moving fluid through the fluid flow path (or at least one of the first device and the second device as recited in Claim 8) comprises a variable-throughput device. Lockwood teaches a wound treatment system wherein the irrigation source may be operated at various pressures (Col. 11 lines 31-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Risk with Lockwood for the purpose of being able to wash off more debris from the wound as deemed necessary by the physician.

With regard to Claim 20, Risk teaches an apparatus for aspirating, irrigating and/or cleansing wounds, comprising:

a backing layer (602) capable of forming a fluid-tight seal over a wound;

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a fluid supply tube (18) arranged to provide fluid from a fluid reservoir to the wound;

a fluid offtake tube (20) arranged to withdraw fluid from the wound;

a pump (110 or syringer 24 with plunger 70) in communication with at least one of the fluid supply tube and the fluid offtake tube and configured to move fluid through at least one of the fluid supply tube and the fluid offtake tube; and

a regulator (50) in communication with at least one of the fluid supply tube and the fluid offtake tube and configured to at least regulate the rate of fluid flowing through at least one of the fluid supply tube and the fluid offtake tube;

Risk does not explicitly teach that the apparatus is *configured to provide simultaneous* aspiration and irrigation to the wound but rather teaches that the aspiration and irrigation are done alternately (Col. 10 line 49 to Col. 11 line 16).

Lockwood teaches a wound treatment system that allows for simultaneous irrigation and aspiration (Col. 17 lines 53-58). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Risk with Lockwood for the purpose of preventing bacterial growth.

With regard to Claims 21 and 24, Risk also teaches that the regulator is a valve (130, which is controlled by controller 50) or a pump (syringe 24 with plunger 70 pump fluid out based on controls by controller 50).

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With regard to Claim 22, Risk also teaches that the pump (in this case syringe 24 and plunger 70) is in communication with the fluid supply tube and is configured to move fluid through the fluid supply tube, and the regulator (130 is controlled by controller 50) is in communication with the fluid offtake tube and is configured to regulate the rate of fluid flowing through the fluid offtake tube and to move fluid through the fluid offtake tube.

With regard to Claim 23, Risk also teaches that the pump (in this case syringe 24 and plunger 70) is in communication with the fluid supply tube and is configured to move fluid through the fluid supply tube, and the regulator is a second pump (110 in this case, the speed of which is regulated by controller 50) in communication with the fluid offtake tube and is configured to regulate the rate of fluid flowing through the fluid offtake tube and to move fluid through the fluid offtake tube.

16. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Risk in view of Harris (US 5,030,202). Risk does not explicitly teach that at least one of regulating the amount of fluid that flows through the fluid supply tube or fluid offtake tube comprises regulating the amount of fluid with a variable speed pump. Harris teaches a medical system that provides aspiration and irrigation to tissue, wherein the system comprises a variable speed pump to control the aspiration rate (Claim 12). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Risk with Harris for the purpose of having an alternative way (compared to using valves) to control the rate at which fluid is delivered to the wound.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 9:00AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
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